7.3 510(k) Summary Statement (21CFR 807.92)

Submitter	American Medical Systems Inc. (AMS) 10700 Bren Road West Minnetonka, MN 55343
Contact Person	Stephanie George Phone (952)-930-6389 Fax (952)-930-5785
Preparation Date	July 14, 2008
Device Common Name	Penile Prosthesis
Device Trade Name	AMS Spectra™ Concealable Penile Prosthesis
CFR Number	21 CFR Part 876.3630
Regulatory Class	Class II (special controls)
Product Codes	78 FAE (penile prosthesis)
Predicate Devices	DURA II® Penile Prosthesis (K953640) AMS 600M™ Malleable Penile Prosthesis (K912935) AMS 650™ Malleable Penile Prosthesis (K951716)

OCT 20 2008

Indications for Use

The AMS Spectra™ Concealable Penile Prosthesis is a sterile, non-pyrogenic, single-use implant that is intended for use in the treatment of chronic, organic, erectile dysfunction (impotence) in men who are determined to be suitable candidates for implantation surgery.

Device Description

The AMS Spectra™ Concealable Penile Prosthesis consists of a pair of cylinders which are surgically implanted, one into each corpus cavernosum, to provide penile rigidity. Each device consists of two cylinders and may include rear tip extenders (RTEs) for additional length. All components consist of implantable, biocompatible materials.

The cylinder consists of a malleable section of articulating polymer segments. A cable extends through the center of the articulating segments. The proximal and distal ends of the cable are each connected to a spring that is encased in a metal housing. The entire outside surface of the cylinder is made of silicone.

The articulating segments, held together by the cable and spring assemblies, provide sufficient friction and rigidity. This allows the patient to position the device for concealment or for intercourse.

Spectra cylinders are available in 9.5-, 12-, and 14-mm diameters. Each cylinder diameter is available in three lengths: 12-, 16-, and 20-cm.

The total cylinder length can be adjusted by adding rear tip extenders (RTEs) to the proximal cylinder end. A range of RTE lengths is included to accommodate the patient's total intracorporal length.

Rear tip extenders may be attached to the Spectra™ cylinders in 0.5-cm increments, and may extend the cylinder lengths from 0.5- to 7.5-cm, with the exception of 7-cm. The RTEs are the same as those used with the inflatable AMS 700™ CXR and CX/LGX models (D970012.) These RTE components' functional performance has been demonstrated in use with the 700™ IPP products.

Substantial Equivalence

The AMS Spectra™ Concealable Penile Prosthesis was subjected to performance tests to evaluate its function. These tests included evaluations of cycle life, springback angle, column strength (rigidity), bend force, bond strength, packaging, sterilization, biocompatibility, and cadaveric evaluation with physicians. For each test, acceptance criteria were established prior to testing. The outcome of each test was that the acceptance criteria were met by the Spectra™ product, demonstrating substantial equivalence to the predicate products.

Because the intended use and the fundamental scientific technology of the predicate DURA II® and AMS 600M™ and 650™ Malleables were maintained with the AMS Spectra™, a clinical study was not conducted for Spectra™.

The nonclinical performance tests demonstrated that the Spectra™ device is as safe, as effective, and performs as well as or better than the legally marketed DURA II® and AMS 600M™ and 650™ Malleable penile prostheses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 20 2008

Ms. Stephanie George
Regulatory Affairs Specialist
American Medical Systems
10700 Bren Road West
MINNETONKA MN 55343

Re: K082006
Trade/Device Name: AMS Spectra™ Concealable Penile Prosthesis
Regulation Number: 21 CFR §876.3630
Regulation Name: Penile rigidity implant
Regulatory Class: II
Product Code: FAE
Dated: October 14, 2008
Received: October 15, 2008

Dear Ms. George:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

7.2 Statement of Indications for Use

Indications for Use

510(k) Number (if known): ~~Unknown~~ K082006

Device Names: AMS Spectra™ Concealable Penile Prosthesis

Indications For Use: The AMS Spectra™ Concealable Penile Prosthesis is a sterile, non-pyrogenic, single-use implant that is intended for use in the treatment of chronic, organic, erectile dysfunction (impotence) in men who are determined to be suitable candidates for implantation surgery.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number _____